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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,776	02/26/2002	Stephen A. Ulrich	ORT-1587	5483

7590

08/26/2003

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,776

Applicant(s)

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Examiner acknowledges receipt of declaration and request for extension of time filed 07/30/02, IDS filed 11/12/02 and election filed 05/23/03.

Election Requirement

Examiner thanks the applicants for electing without traverse sucralose and for identifying the claims that read on the elected sucralose. Upon further consideration, many compositions defined by different sweeteners, thickening agents and forms of compositions can be identified. Thus, a further election is required and all the pending claims have been examined in order to expedite prosecution (see item number 20 of this action).

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 4-10, 14-73 and 80-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 5-7 recite "---type" and the "type" makes the claims vague and indefinite because the claims include elements not actually disclosed by those encompassed by "type", thereby rendering the scope of the claims unascertainable. See *Ex parte Copenhaver*, POBA, 1955, 109 USPQ 118-119. What does the term "type" do to, for example "macrolide antibiotic"? The term type may be deleted from the claims at wherever the term appears in the claims.
4. Claims 21-23, 31, 32, 44; 52-55; and 80-74 all depend from claim 1, and in claim 1, the taste masking composition is not further defined. But claim 20, for example, recites "further

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comprises” and claim 1 does not define the taste masking composition and as such the taste masking composition of claim 1 cannot further comprise taste masking effective amount of ---.

It is suggested that the “further” be deleted from these claims so that the composition of claim 1 comprises taste masking effective amount of ---; the claims are thus examined as comprising ---.

5. Claims 4-7 recite the limitation "the bitter tasting" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite “bitter tasting” and there is no antecedence for the “bitter tasting.”
6. Claim 14 recites the limitation "the artificial sweetener" in line 1. There is insufficient antecedent basis for this limitation in the claim. There is no recitation for “artificial sweetener” in claim 1.
7. Claims 15-19 recite the limitation "taste masking effective amount of aspartame", "taste masking effective amount of acesulfame", "taste masking effective amount of cyclamate" and "taste masking effective amount of saccharin" respectively in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. There is no recitation of “effective amount of aspartame” or a recitation of “aspartame” in claim 1.
8. Claims 20-22 recites the limitation "taste masking effective amount of sucralose" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. There is no recitation of “effective amount of sucralose” or a recitation of “sucralose” in claim 1.
9. Claims 31 and 44 recite the limitation "the artificial sweetener" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not have a recitation for “artificial sweetener.

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10. Claims 53, 55 and 82 recite the limitation "the artificial sweetener sucralose" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-10, 13, 14, 23, 24, 27, 28, 32-34, 38, 40, 44, 74-79, 81-83, rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al. (US 6,482,823).

Yu discloses a taste masked liquid composition that comprises a coated pharmaceutical composition and the coating composition comprises a polymer blend; the pharmaceutical is levofloxacin or ofloxacin or related quinolone antibiotic (abstract, column 2, lines 15-34). One or more pharmaceutically acceptable adjuvants such as flavorings, sweeteners, thickening agents, coloring agents are mixed with the taste coated levofloxacin; the sweeteners are sucrose, maltitol, sorbitol, saccharin, aspartame or acesulfame K and the composition is formulated as a liquid or powder for reconstitution with water into a liquid formulation (claim 11, column 3, lines 7-19 and 29-40 and column 4, lines 25-36). The compositions on Table 4 contain 2.5 grams and 5 grams of levofloxacin per 100 ml. One or more pharmaceutically acceptable adjuvants (claim 11) meet the limitation of instant claim 27 further requiring up to two flavoring

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agents. An effective amount without the recitation of specific amount is any amount that is taught or not taught by the prior art. The teaching of Yu meets the limitations of the claims.

13. Claims 1-4, 13, 14, 20-27, 44, 74-77 and 79-84 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee (US 6,391,886).

Lee discloses an oral liquid composition that comprises antibiotics (column 3, lines 47), sucralose and second sweetener selected from the group consisting of saccharin, acesulfame K, aspartame and mixtures thereof (column 4, lines 1-60 and claims 1-17). Sucralose is in amounts of 0.4% to and saccharin or aspartame or acesulfame is in amounts of 0.0001% to 1.5% (column 4, lines 30-58). The teachings of Lee meet the limitations of the claims.

14. Claims 1-6, 13, 14, 31-35, 38, 40, 44, 74-77 and 79 rejected under 35 U.S.C. 102(b) as being anticipated by Lienhop et al. (US 5,730,997).

Lienhop discloses taste masked liquid pharmaceutical composition that comprises pharmaceutical agents such as ciprofloxacin, ofloxacin, pefloxacin and macrolide antibiotics (column 4, lines 5-17), hydrogenated maltose syrup (column 4, line 62, column 5, lines 12 and 13), polysaccharide sweetening agents such as xylose, ribose, sucrose, sugar, sorbitol, xylitol, mannitol and mixtures thereof (column 6, line 66 to column 7 line 5) or artificial sweetening agents such as saccharin, cyclamate, acesulfame K (column 7, lines 6-10). Sweeteners mask bitter taste of bitter tasting drugs or medicines and thus act as debittering agents. Thus the teaching of Lienhop meets the limitations of the claims.

15. Claims 1-5, 45-52 and 56-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al. (US 6,239,141).

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Allen discloses a suspension comprising water, trovafloxacin, a quinolone antibacterial agent, one or more suspending or thickening agents in any suitable concentration and sweetening, buffering and flavoring agents (column 10, lines 22-24 and column 6, lines 27, 28 and 39-44). The suspending or thickening agents are xanthan gum, guar gum, locust bean gum, tragacanth gum, carboxymethylcellulose and hydroxypropylcellulose (column 10, lines 26-38). The teaching of Allen meets the limitations of the claims.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 11, 12, 15, 16, 18, 19, 25, 26, 29, 30 and 41-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. (US 6,482,823).

Yu clearly teaches the instant composition by failed to teach the specific amounts recited in the designated claims. However, there is no data showing that the specific amounts of the sweeteners provide unusual results to the taste masked composition and differences in amounts or concentrations of ingredients in a composition does not patentably distinguish the invention over the prior art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare taste masked levofloxacin composition where the composition comprises the levofloxacin and sweeteners. One having ordinary skill in the art

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would have been motivated to incorporate appropriate amounts of sweeteners in the composition with the expectation that the taste of the bitter levofloxacin will be masked.

18. Claims 17, 36, 37 and 45-55 rejected under 35 U.S.C. 103(a) as being unpatentable over Lienhop et al. (US 5,730,997).

Lienhop teaches the instant composition except that Lienhop does not teach a suspension. However, in column 1, lines 18 and 19, Lienhop discloses that pharmaceutical compositions are administered to patients as liquids and suspensions and emulsions as well as solids. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the liquid composition of Lienhop. One having ordinary skill in the art would have been motivated to prepare the Lienhop composition as an emulsion or suspension according to the suggestion of Lienhop with the expectation of easier delivery of a taste masked antibiotic ciprofloxacin to patients who may have difficulty in swallowing such as children and older patients.

19. Claims 59-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (US 6,239,141).

Allen teaches the instant composition except that the prior art does not teach a mixture of microcrystalline cellulose and carboxymethylcellulose as a thickening agent. However, a composition comprising trovafloxacin and microcrystalline cellulose and cross-linked carboxymethylcellulose is known (column 4, lines 18-20). Regarding the amount of xanthan gum in the trovafloxacin composition, one of ordinary skill in the art would know routine experimental ways of using the appropriate amounts of xanthan gum that would thicken the composition to give the desired suspension. Regarding, claim 64, sodium

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carboxymethylcellulose, a salt form of the carboxymethylcellulose can be used in place of carboxymethylcellulose as a thickening agent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a taste masked trovafloxacin composition that comprises trovafloxacin, carboxymethylcellulose and sweetening and flavoring agents. One having ordinary skill in the art would have been motivated to use a mixture of carboxymethylcellulose and microcrystalline cellulose in the appropriate amounts with the expectation that a suspension of trovafloxacin of the desired viscosity and consistency is formed that is suitable for oral administration.

20. This application contains claims directed to the following patentably distinct species of the claimed invention: Many taste masked liquid pharmaceutical compositions are claimed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed taste masked composition for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

21. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent examiner
Tech. Center 1600

